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To: Carole Williams

From: Joy Pelletier

Re: copy of oral statement from April 4 public meeting

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PRESENTATION OF JOY PELLETIER
BEFORE THE FOOD AND DRUG ADMINISTRATION

My name is Joy Pelletier. I am a biochemist and nutrition scientist employed by Pure Encapsulations, Inc. of Sudbury, Massachusetts. I advise the company on product formulations, on the scientific evidence concerning product ingredients, and on permissible claims. I spend most of my time reading peer-reviewed scientific journals in biochemistry and nutrition science.

Nutrient-disease information need not be proven conclusively true to be accurately represented to the public. The *Pearson* Court understood that First Amendment lesson. This agency still does not.

In the course of my work I frequently encounter nutrition science which, although not conclusive, strongly associates a nutrient with reduction in the risk of a particular disease or reduction in certain disease symptoms. That accurate information is not of the kind FDA approves under its health claims review standard. In other words, although a nutrient-disease assocation can be accurately stated, FDA prohibits it until the association is proven conclusively.

To follow the law, companies such as the one I represent deprive consumers of truthful answers to nutrient-disease association questions every day. We know that truthful answers on the nutrient-disease association will violate FDA's health claims ban which judges speech on conclusiveness, not on truth.

FDA's health claims rule has blocked from consumers a wealth of accurate scientific information contained in the peer-reviewed literature that indicates certain nutrients may affect certain diseases. The nation's leading scientists and even the Surgeon General may rely on that information and accurately inform patients of the possibility that Vitamin E may reduce the risk of heart disease; that Saw Palmetto may relieve the symptoms of benign prostatic hypertrophe; that Vitamin B6, Vitamin B12, and Folic Acid may reduce the risk of vascular disease; that ginger may eliminate nausea; or that prune juice may relieve chronic constipation but that same information cannot appear on the label or in the labeling of a dietary supplement.

The ones hurt most by FDA's health claims rule are consumers. Consumers buy dietary supplement for health reasons. They perform a basic risk benefit analysis before making a purchase. If the product is safe, and it may help reduce disease risk or reduce disease symptoms, even if the jury is still out, they may still give it a try.

Consumers are far more sophisticated than FDA believes. They appreciate that very little in science is proven conclusively true, yet much in science not proven conclusively is still of great potential use. Thus, most oncologists in the United States consume antioxidant vitamins. They know well that the scientific evidence that antioxidants reduce the risk of cancer is very strong but may not yet be conclusive. Thus, most cardiologists in the United States consume Vitamin E. They know well that the

scientific evidence that Vitamin E reduces the risk of heart disease is very strong but may not yet be conclusive. Yet the risks of consuming these products are zero and the potential benefits are great. In short, it is a safe bet. Consumers are entitled to make those safe bets too, but they can only do so if they are accurately informed. And, they can only be accurately informed if FDA embraces the *Pearson* decision and discloses this information rather than suppresses it.

The *Pearson* Court has ordered FDA to get out of the business of suppression and into the business of disclosure. This agency has to do a 180 degree turn around and start fostering the distribution of accurate health claims rather than blocking all health claims it deems inconclusive.

Consider the consequences of FDA's prohibition on the dissemination of inconclusive, yet accurately stated science.

First, the absence of accurate science at the point of sale deprives consumers of information they need to make informed choices. When deprived of accurate nutrient-disease information at the point of sale, consumers are bound to be misled by erroneous assumptions derived from secondary sources (magazines, newspapers, radio, television).

Second, the absence of accurate science at the point of sale increases the chance that consumers will harm themselves by consuming too much of a product or by avoiding a needed medical treatment.

Third, the absence of accurate science at the point of sale increases the chance that consumers will be defrauded. Without accurate information, consumers are less likely to be skeptical about false claims.

Fourth, by prohibiting all but those claims that are proven to a near conclusive degree, FDA has created a huge black market in unapproved claims. By implementing the *Pearson* decision and allowing inconclusive claims with disclaimers, FDA will lower the bar and cause many who now avoid claim submission to file claims. Thus, more accurate information will reach consumers than ever before.

In sum, FDA's effective ban on all but conclusive nutrient-disease information at the point of sale not only violates the First Amendment rights of people like me but also endangers public health. It leaves fraud and misinformation in the market unchecked by accurate information.

Remember, nutrient-disease information need not be proven conclusively true to be accurately represented to the public. The *Pearson* Court understood that First Amendment lesson. This agency still does not.